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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,562	01/16/2004	Prabha Ibrahim	01-0159-CIP2	8096
27716	7590	03/29/2005	EXAMINER	
CV THERAPEUTICS, INC.			OWENS, AMELIA A	
3172 PORTER DRIVE			ART UNIT	PAPER NUMBER
PALO ALTO, CA 94304			1625	

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/759,562	IBRAHIM ET AL.	
	Examiner	Art Unit	
	Amelia A. Owens	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 25-27 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24,28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-29 are pending. No drawings were filed with the application. No foreign priority was claimed.

Election

Applicant's election without traverse of Group I, claims 1-24 and 28 in the reply filed on February 23, 2005 is acknowledged.

Claims 25-27,29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 23, 2005.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

The examiner has considered the IDS submitted 5/2/2004; 9/13/2004; 2/9/2005.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

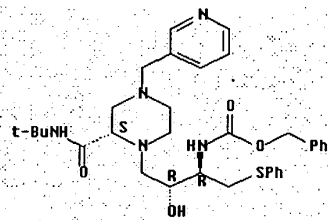
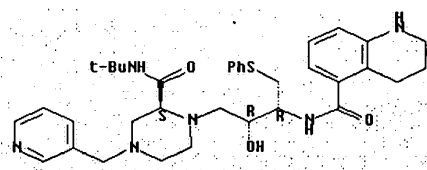
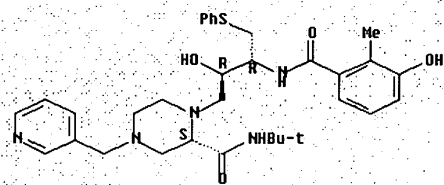
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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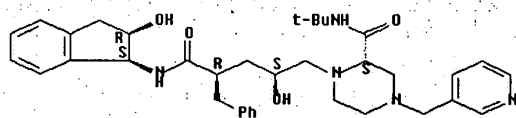
²⁸
 Claims 1, ~~2~~, is rejected under 35 U.S.C. 102(b) as being anticipated by several references listed below. *The compounds are pharmaceuticals.*

Dressman et al CA 124:317888 which teach several species according to the invention.

See abstract. A few are exemplified. Note for the species Z2 = substituted alkylene; Z1 alkylene; Y = monocyclic heteroaryl (pyridine); T = sulfur; X2 = aryl; X1 = hydrogen; one of positions R3/R4 is C(O)R where R is NR9(R10) where R9/R10 are hydrogen/lower alkyl respectively.

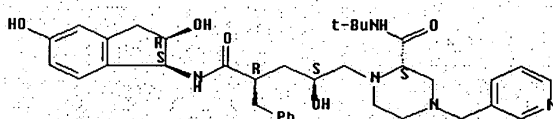
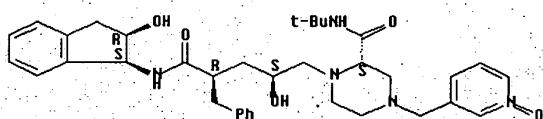
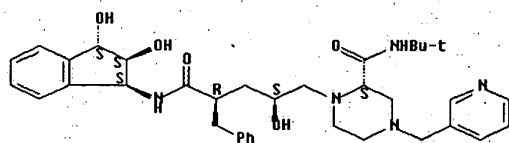


Lloyd CA 131:82953 which teach species according to the invention.

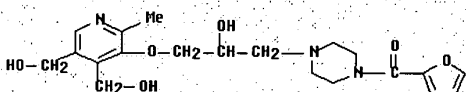


Shafiee et al CA 125:114698 teach several species according to the invention. A few are exemplified. See abstract.

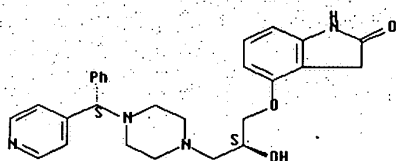
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Urbain et al (CA 98:46434) teach species according to the invention. Note Z1 is alkylene substituted by carboxyl; T = oxygen; X2 = substituted pyridyl; Z2 = methyl; X1 = hydrogen.

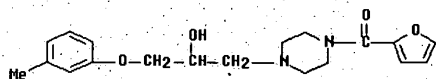


Berthold et al (CA 106:84635 AND CA 105:172505) teach several species according to the invention. Because of the many species only one (1) is exemplified. *See both abstracts*. In particular note that Y = optionally substituted monocyclic heteroaryl; Z1/Z2= optionally substituted alkylene; T = oxygen; X2 = optionally substituted heteroaryl or optionally substituted aryl.



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Fan et al (CA 108 :5971) teach species according to the invention. See abstract. Note that Z1 is alkyl substituted by oxygen; y is monocyclic heterocycle; Z2 is alkyl; T is oxygen; X2 is optionally substituted aryl.



Claims 2-24, ~~25~~ are not included in the rejection as the reference does not teach the specific embodiments.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-24,28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29,33 of copending Application No. 10/759,555. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to the same generic concept.

Application '555 teach compounds which differ from present claims by defining Y as optionally substituted monocyclic dihydroheteraryl all other variables are the same. The instant claims define Y as optionally substituted heteroaryl. See app. '562 at page 16 para. 41 which defines 'heteroarylene' and gives an example of an unsaturated group..... See app. '555 at page 14 lines 9-12 which defines 'dihydroheteroaryl' as --- a heteraryl group in which one

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double bond has been saturated and one double bond remains unsaturated. Note these definitions overlap in the groups covered.

One of ordinary skill in the art would be motivated to prepare the claimed compounds given app. '555 since the definitions overlap. The compounds have the same utility, ie treating cardiovascular diseases. No unobvious or unexpected results are noted.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-24,28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4,6-22,24-29 of copending Application No. 10/198,237. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to the same generic concept.

App. '237 teach compounds where all other variables are identical and the definition of X1 and X2 overlap rendering the same invention. The compounds have the same utility, ie treating cardiovascular diseases. *For '237 X1 = opt. Sub. Aryl; for '562 X1 = hydrogen.....opt. Sub. Aryl, For '237 X2 = opt subs heteroaryl; for '562 X2 = opt. Sub. Aryl or heteroaryl.*

One of ordinary skill in the art would be motivated to prepare the claimed compounds given app. '237 since the definitions overlap rendering the same group of compounds. No unobvious or unexpected results are noted.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Claims 1-24, 28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,3-35,43 of copending Application No. 10/346,684. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to the same generic concept.

App. '684 teach compound that differ from app. '562 only in definition of V. In '684 V is limited to nitrogen while in '562 V is nitrogen or carbon.

Motivation for one of ordinary skill in the art to prepare the claimed compounds given app. '684 is the overlap in scope. Further, the compounds have the same utility, treating cardiovascular disease. No unobvious or unexpected results are noted.

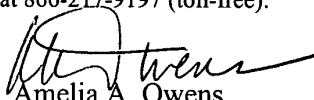
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant is reminded in amending the claims to avoid new matter situations.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amelia A. Owens whose telephone number is 571-272-0690. The examiner can normally be reached on Monday - Friday from 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Amelia A. Owens
Primary Examiner
Art Unit 1625